

1060-133 Are Acute and Late Clinical Outcomes in the Elderly Different in the New Device Angioplasty Era?

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Important decisions regarding resource allocation will depend upon risk-benefit analyses in specific patient populations, especially the elderly. To determine clinical outcome variables after catheter-based coronary interventional procedures in the elderly, we analyzed 5,355 consecutive patients from 1992 to 1996 treated using balloon PICA or new device angioplasty (60%).

In-Hospital Events	< 70 yrs (N = 3860)	70-80 yrs (N = 1265)	> 80 yrs (N = 230)	p
Proc success	96%	96%	95%	NS
Death	0.8%	2.4%	4.2%	<0.0001
Q-wave MI	0.9%	0.8%	1.9%	NS
CABG	1.4%	1.2%	0.7%	NS
Vasc comp.	5.0%	8.0%	8.7%	<0.0001
Stroke	0.3%	0.7%	2.3%	<0.0001
CHF	1.9%	4.3%	6.9%	<0.0001
Renal failure	2.3%	6.2%	7.3%	<0.0001

Vascular complications (Vasc comp) = surgical repair + transfusion

During long-term (> 6 months) clinical follow-up, there was a stepwise increase in death in the elderly (2.7% vs. 6.5% vs. 11.4%, $p < 0.0001$), mainly due to non-cardiac causes, but no increase in MIs or repeat revascularization events. *We Conclude:* In the new device era, elderly patients (1) have excellent procedure success, but higher in-hospital mortality and non-cardiac complications; and (2) late outcomes indicate continued high mortality, but similar repeat revascularization events.

1060-134 Therapeutic Ultrasound Coronary Angioplasty - Only Dotter Effect?

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Coronary ultrasound angioplasty (USA) is a new therapeutic interventional device for coronary arteries. Energy of 16-20 W at 19.5 kHz is supplied through a 1.2 or 1.7 mm ball tip catheter during longitudinal vibrations of 16-20 μ m. To assess the effect on vessel wall and plaque, intravascular ultrasound imaging was performed in 21 consecutive patients (pts.) undergoing USA with the 1.7 mm catheter for symptomatic coronary artery disease.

Results: After USA in 19/21 lesions with mixed plaque configuration the lumen diameter was 1.7 + 0.2 mm. In 2 lesions with soft thrombotic material an eccentric lumen enlargement was found (2.2 and 2.8 x 1.7 mm diameter). In 19/21 lesions the inner plaque contour was found to have an unusual sharp contour. In 7 lesions a new circular echodens phenomenon reaching from the borderline of the inner lumen/intima up to 0.3 mm into the plaque was detected. There was no evidence of dissection but intima splitting in 4 lesions. After adjunctive low pressure PTCA in 19/21 lesions the inner contour remained smooth in 8 lesions, 1 dissection and 3 new intima splittings were detected.

Summary: 1) After coronary ultrasound angioplasty a smooth inner contour of the intima is regularly found. 2) In about one third of the lesions a new circular echodens zone at the inner border (intima/inner lumen) can be assessed. 3) The lumen size after ultrasound angioplasty has the size of the catheter in patients with mixed plaque; it is more increased in soft plaque lesions.

Conclusion: There is a direct effect of the coronary ultrasound angioplasty to the inner lumen/plaque that can not be explained with dotter effect alone.

1060-149 Cutting Balloon Angioplasty vs. Plain Old Balloon Angioplasty Randomized Study in Type B/C Lesions (CAPAS)

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To evaluate the efficacy and safety of cutting balloon angioplasty (CB) for type B/C lesions, a prospective randomized trial was designed. This study started in Nov. 1995 and 151 lesions were enrolled by Aug. 1996. Inclusion criteria were as follows; type B/C lesions (ACC/AHA classification), reference diameter (RD) < 2.8 mm. Exclusion criteria were as follows; heavily calcified lesion, severely bent lesion and AMI culprit lesion. Furthermore, lesions with incomplete balloon expansion or interrupted and severe dissection requiring stenting were defined as drop-outs. 151 lesions were divided into two groups (CB: 76, POBA: 75 lesions). Eligible lesions were 76% (58/76) in

CB and 77% (58/75) in POBA. Quantitative Coronary angiography (QCA) was to be performed at pre, post-PTCA and 3 months follow-up (3 M) using Cardiovascular Measurement System Ver.3 (CMS). Baseline QCA data were not different in the 2 groups [RD; 2.1 ± 0.3; 2.2 ± 0.4 mm, minimal lumen diameter (MLD); 0.6 ± 0.4; 0.7 ± 0.2 mm, % diameter stenosis (% DS); 70 ± 15; 75 ± 10% (CB: POBA)]. Post-QCA data were also not different [MLD; 1.6 ± 0.4; 1.5 ± 0.4 mm, % DS; 24 ± 14; 32 ± 13%, Balloon/Artery ratio; 1.3 ± 0.2; 1.2 ± 0.2 (CB: POBA)]. There were no major in-hospital complications in the 2 groups. 3M-QCA data were not different [MLD; 1.2 ± 0.4; 1.2 ± 0.4 mm, % DS; 46 ± 14; 53 ± 13% (CB: POBA)]. Target lesion revascularization (TLR) rate was 30% (13/44) in CB and 41% (18/44) in POBA.

Conclusion: Cutting balloon angioplasty was performed safely compared to plain old balloon angioplasty for type B/C lesions. As for initial success, there were no remarkable differences between the 2 groups. But, 3 M data (TLR) would suggest CB for type B/C lesions may reduce restenosis.

1060-150 Clinical Evaluation of the Coronary Pullback Atherectomy Catheter: Procedural Results and Late Clinical Follow-up

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The coronary Pullback Atherectomy Catheter (PAC) is a novel atherectomy device with a 360 degree cutting circumference designed to excise plaque using a single retrograde pass through the lesion. We evaluated the safety and clinical efficacy of PAC in 40 patients with 42 lesions (LAD, n = 16; LCX, n = 10; RCA, n = 13; SVG, n = 3). Quantitative coronary angiography was completed at baseline, post PAC, after adjunctive therapy and at 6 months post-procedure.

	MLD (mm)	% Stenosis
Baseline	0.93 ± 0.29	69 ± 10
Post-PAC	1.77 ± 0.51 [†]	46 ± 13 [†]
Final	2.76 ± 0.58 [†]	17 ± 8 [†]
6 Months*	1.75 ± 0.56 [†]	40 ± 16 [†]

*Data from 11 patients; [†]p < 0.001 versus baseline

Initial procedural success (< 50% diameter stenosis, without death, QWMI or CABG) was achieved in all cases. Plaque (mean tissue weight 8.8 ± 9.0 mg) was removed from 40 of 42 (95%) lesions. The weight of the excised tissue positively correlated with the PAC to artery ratio (r = 0.58, p = 0.007). On histology, media or adventitia was identified in 24 of 40 (60%) specimens. Adjunctive therapy was required in all cases. Stent placement was performed in 23 patients to optimize angiographic results and to treat 2 acute vessel closures. CK-MB enzyme elevations ≥ 2 times normal occurred in 4 patients. At a mean of 7 months follow-up there were no deaths or QWMI. Target lesion revascularization was required in 5 (12.5%) patients.

Conclusions: PAC in conjunction with PTCA or stenting is safe and effective for the treatment of symptomatic obstructive lesions in coronary arteries. Late clinical and angiographic follow-up in this phase I study are nearing completion.

1060-151 Does Gender Affect Outcome in the New Approaches to Coronary Intervention (NACI) Registry

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Increased risk for procedural mortality was shown in women after balloon PTCA in the 1985-86 NHLBI PTCA Registry. To assess the procedural and late risk for women after planned new device angioplasty (atherectomy,

	Men	Women
Number: Patient/lesion	1983/2218	1076/1218
AHA/ACC: A-B1/B2-C	29/71	31/69
Dissection > A: Pre/Worst	3/17	3/20
Reference diameter mm	3.18	3.04 [†]
MLD Pre/Final mm	0.91/2.45	0.94 [†] /2.36 [†]
% Stenosis Pre/Final	71/24	69/24
Angiographic success %	87	82 [†]
Early CABG %/Death %	1.61/0.96	2.97 [†] /1.30
F/U CABG %/Death %	11.3/ 5.8	11.0/5.5
F/U Q-MI%/RePTCA %	2.2/23.7	1.6/20.9
Any F/U Death/QMI/Revasc %	40.4	35.1 [†]